# Prospective randomized controlled clinical study comparing two types of two-piece dental implants supporting fixed reconstructions-Results at 5 years of loading

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Abstract: OBJECTIVES Compare clinical outcomes of two types of dental implants with non-matching implant-abutment junctions loaded with fixed implant-borne reconstructions at 5 years of loading. MATERIALS AND METHODS In 64 patients, one of two implant systems (S1, S2) was randomly used to support fixed dental prostheses (FDP). At loading ($T_L$ ), after 1 ($T_1$ ), 3 ($T_3$ ) and 5 years ($T_5$ ), the implant and reconstruction survival, biological and technical complications, radiographic marginal bone levels, clinical outcomes were recorded. The implants of the groups S1 and S2 contained of two-piece titanium implants with a non-matching implant-abutment junction. Data were analyzed on the patient level (1 implant/patient) using the non-parametric Wilcoxon-Mann-Whitney test. RESULTS Ninety-seven implants were placed and loaded with fixed reconstructions in 64 patients. At $T_5$ , 29 S1 and 28 S2 implants were available for the patient-level analysis. Two implants in group S1 had to be removed in the same patient due to severe peri-implantitis, resulting in a survival rate of 96.1% on the implant level and 96.6% on the patient level. No implant in group S2 was lost. The technical complication rate on patient-level amounted of 24.2% (S1) and of 6.5% (S2) ($p > .05$). Biological complications on patient-level were observed in 15.2% (S1) and 16.1% (S2) ($p > .05$). From TL to T5, the medians of the mean marginal bone level changes wer a gain of 0.15 mm in group S1 and a loss of 0.14 mm in group S2 ($p > .05$). CONCLUSIONS AND CLINICAL IMPLICATIONS Both implant systems revealed high survival rates and minimal changes of the marginal bone levels during 5 years. Few biological complications occurred in both groups. S1 revealed a high rate of technical complications. Therefore, both implant systems can be recommended for fixed reconstructions.

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# Prospective randomized controlled clinical study comparing two types of two-piece dental implants supporting fixed reconstructions – results at 5 years of loading.

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Running title: Randomized controlled study comparing two-piece implant systems

**Key words:** dental implants, fixed partial denture, marginal bone level, survival, biological complications, technical complications

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## Abstract

**Objectives:** Compare clinical outcomes of two types of dental implants with non-matching implant-abutment junctions loaded with fixed implant-borne reconstructions at 5 years of loading.

**M&M:** In 64 patients one of two implant systems (S1, S2) was randomly used to support fixed dental prostheses (FDP). At loading ($T_L$), after 1 ($T_1$), 3 ($T_3$) and 5 years ($T_5$), the implant and reconstruction survival, biological and technical complications, radiographic marginal bone levels, clinical outcomes were recorded. The implants of the groups S1 and S2 contained of two-piece titanium implants with a non-matching implant abutment junction. Data were analyzed on the patient level (1 implant/patient) using the non-parametric Wilcoxon-Mann-Whitney-test.

**Results:** Ninety-seven implants were placed and loaded with fixed reconstructions in 64 patients. At $T_5$, 29 S1 and 28 S2 implants were available for the patient level analysis. Two implants in group S1 had to be removed in the same patient due to severe peri-implantitis, resulting in a survival rate of 96.1% on the implant level and 96.6% on the patient level. No implant in group S2 was lost. The technical complication rate amounted of 24.2% (S1) and of 6.5% (S2) ($p>0.05$). Biological complications were observed in 15.2% (S1) and 16.1% (S2) ($p>0.05$). From $T_L$-$T_5$, the medians of the mean marginal bone level changes were 0.25mm (S1) and 0.30mm (S2) ($p>0.05$).

**Conclusions:** Both implant systems revealed high survival rates and minimal changes of the marginal bone levels during 5 years. Few biological complications occurred in both groups. S1 revealed a high rate of technical complications. Therefore, both implant systems can be recommended for fixed reconstructions.

## Introduction

The use of dental implants to support fixed dental prostheses (FDP) has become a standard procedure in many dental practices. Clinical indications mainly encompass: i) unsplinted and splinted implant-supported single crowns (ISSC) ii) implant-supported multi-unit FDPs (MUFDP) and iii) implant-supported FDPs with cantilever extensions (ICFDP). Currently, hundreds of implant systems are available on the market. Clinicians have to select from more than 2000 dental implant types and the respective prosthetic reconstructions for a specific clinical indication (Jokstad, et al., 2003). Generally, the implants differ in material, shape, diameter, length, platforms, surface properties and coatings (Binon, 2000; Esposito, Worthington, Thomsen, Coulthard, 2003). It is obvious that the clinician's decision-making process for a certain type of implant is difficult. Evident clinical factors, such as surgical and prosthetic possibilities and overall costs, influence the clinician's choice for a specific implant type and system. Likewise, scientific criteria, such as survival and success rates available from short- and long-term clinical studies on the implant and on the restorative level should play a crucial role in the selection process.

Despite the numerous marketed implant systems, well-performed clinical data are available for 10 implant brands only (Derks, et al., 2016; Jokstad, et al., 2003; Jung, Zembic, Pjetursson, Zwahlen, Thoma, 2012). A Cochrane review reported on the objective to evaluate differences in the clinical performance between various root-formed dental implant types (Esposito, Ardebili, Worthington, 2014). That systematic review included 27 randomized controlled clinical trials (RCTs). In total, 38 different implant types were compared with an observation period ranging from 1 to 10 years. All included studies inserted implants made of commercially pure titanium with different shapes and surfaces. The evidence did not reveal superiority of any of the implant systems analyzed, reporting no statistically significant differences for implant failures and marginal bone level changes on the implant and restorative level. However, it was concluded that more well-designed, long-term RCTs fulfilling the CONSORT statements (Moher, et al. 2010) are required to prove if there is any design, surface modification or material available and able to significantly improve the effectiveness of implant therapy

(Esposito, et al., 2014).

The aim of the present study was therefore, to compare the clinical, radiographic and prosthetic outcomes of two types of dental implants with non-matching implant-abutment junctions loaded with fixed implant-borne reconstructions at 5 years of loading. The null-hypothesis was that the groups S1 and S2 do not differ regarding the medians of the mean marginal bone level changes over 5 years.

## Material and Methods

This article is reported according to CONSORT guidelines for reporting parallel group randomized trials (Moher, et al., 2010).

### Study design

The present study was designed as a prospective randomized controlled clinical trial with two parallel study groups and a duration period of 5 years and was conducted at the Clinic of Fixed and Removable Prosthodontics and Dental Material Science Center of Dental Medicine, University of Zurich, Switzerland. The local ethical committee approved the clinical study protocol (Ref. Nr. KEK-ZH-Nr. 2013-0121). The 1-year results have previously been reported (Ebler, Ioannidis, Jung, Hammerle, Thoma, 2016).

### Study population

Sixty-four patients in need of dental implant therapy with fixed dental prostheses were consecutively enrolled in the study after having signed the informed consent. The enrolled patients had to fulfill the following inclusion criteria:

- Patients had to be healthy and of legal age
- No local jaw pathology
- No periodontal disease (periodontal probing depths < 4 mm)
- Good oral hygiene (full mouth plaque index < 25%) (O'Leary, Drake, Naylor, 1972)
- Adequate control of inflammation (full mouth bleeding on probing < 25%) (Ainamo, Bay, 1975)
- Implant therapy with fixed reconstructions planned

No restrictions were made with respect to the location of the implant(s) (upper/lower jaw, anterior/posterior sites) and in terms of the need for bone regeneration prior to or simultaneously with implant placement. Patients not meeting the inclusion criteria were not considered for the study.

**Randomization**

All patients were randomly allocated using a computer-generated randomization list to receive implants from one of two systems: S1 (Osseo Speed implant TX 3.0 – 5.0 S, TX 4.5; Astra Tech Implant System, Dentsply Sirona Implants, Mölndal, Sweden) or S2 (Straumann Bone Level implants 3.3, 4.1, 4.8 mm, SLActive; Straumann AG, Basel, Switzerland). Allocation to the study groups was concealed by using sealed envelopes until the time of the surgical planning of the implants.

**Surgical procedure**

The surgical procedures were performed according to standard protocols and based on the manufacturers' recommendations of the respective implant systems. In general, the implant shoulder was placed at the level of the lingual bone crest. In some cases, due to prosthetic reasons, the sink depth was increased and thus, the implant shoulder was located subcrestally. Depending on the given clinical situation, various implant lengths and diameters were placed. In group S1, the diameters ranged from 3.0 to 5.0 mm and from 6 to 16 mm in length. The diameters in group S1 ranged from 3.0 to 5.0 mm in diameter and from 6 to 16 mm in length. In group S2, diameters varied between 3.3 and 4.8 mm. The implant length was 6 to 15 mm.

Peri-implant bone dehiscence or fenestration defects were grafted with demineralized bovine bone mineral (DBBM) (Bio-Oss Spongiosa; Geistlich Pharma AG, Wolhusen, Switzerland). A resorbable (Bio-Gide, Geistlich Parma AG) or a non-resorbable membrane (Gore-Tex; W.L. Gore & Assoc., Flagstaff, AZ, USA) was used to cover the DBBM particles. In some cases, a synthetic biphasic calcium phosphate (BCP) consisting of a mixture of 60% hydroxyapatite and 40% of beta-tricalcium phosphate (Straumann Bone Ceramic, Institut Straumann AG, Basel, Switzerland) covered with a synthetic bioresorbable polyethylene glycol (PEG) hydrogel membrane (MembraGel, Institut Straumann AG, Basel, Switzerland) was applied. The materials were selected depending on the clinical situation and the surgeon’s preference. Regarding the healing protocol (submerged versus transmucosal healing), no restrictions were made.

**Prosthetic procedure**

The prosthetic procedures were made according to the guidelines of the respective implant system. Screw-retained or cemented reconstructions with different abutments were used based on the clinical situation and the clinician's decision. The day of the insertion (delayed loading) of the final prosthesis was considered as baseline. The follow-up examinations were performed at 1 year, 3 and 5 years after baseline examination. For every patient, an individually designed maintenance program with regular dental hygiene sessions was performed during the entire study period.

**Outcome measures**

For the record of the outcome measures five different time-points were defined:

- $T_i$: immediately after implant insertion
- $T_L$: 1-3 weeks after loading of the implant (baseline)
- $T_1$: 1 year after loading
- $T_3$: 3 years after loading
- $T_5$: 5 years after loading

The examiners of the outcome measures differed from the operators.

*Implant and reconstruction survival*

Implant and reconstruction survival were calculated at the implant- and patient level for the time-point $T_5$ (5 years). Implant survival was defined as the implant being in place and stable, assessed by hand testing. Reconstruction survival was defined as the reconstruction being *in situ*.

*Biological and technical complications*

The incidence of biological and technical complications was assessed at the follow-up visits. As a biological complication peri-implant mucositis (6 BOP positive sites at the implant) and peri-implantitis (change in the marginal bone level > 2 mm between two time-points) were assessed. The recorded

technical complications were: implant fracture, abutment fracture, fracture of the veneering ceramic, loosening of the abutment screw, fracture of the abutment screw. If necessary, appropriate treatment was performed until the complication was resolved.

*Radiographic assessment*

Periapical radiographs were taken immediately after implant insertion ($T_i$), at baseline after loading ($T_L$), at 1 year ($T_1$), at 3 years ($T_3$) and at 5 years ($T_5$). Standardized intraoral radiographs were obtained using a paralleling technique with Rinn-holders and analogue films (Kodak Ektaspeed Plus, Eastman Kodak and Co., Rochester, NY, USA). X-rays were first digitized as .jpeg files and imported in an open source software (ImageJ 1.43; National Institute of Health, Bethesda, MD, USA). Marginal bone levels were assessed at a magnification of 10 – 15×. The pitch distance between two implant threads was used to calibrate and determine the exact magnification of the individual images. The marginal bone level was examined at both the mesial and distal aspect of each implant by measuring the distance between the flat top of the implant shoulder and the bone crest using a scale divided into 0.1 mm steps (= distance implant to bone, DIB). The mean of mesial and distal marginal bone level was then calculated. The changes in MBL from $T_i$ to $T_L$, $T_1$, $T_3$ and $T_5$ were considered and a negative change of MBL denoted a loss of marginal bone.

*Clinical parameters*

At the follow-up examinations, the following variables were assessed at 6 sites per implant (mesiobuccal, buccal, distobuccal, distolingual, lingual and mesiolingual) and averaged (UNC-15, Hu-Friedy, Chicago, IL, USA):

- Probing depth (PD, mm)
- Bleeding on probing (BOP, %) (Ainamo, Bay, 1975)
- Plaque control record (PCR, %) (O'Leary, et al., 1972)

**Statistical analysis**

As the primary outcome for this investigation, the mean marginal bone level change at the patient level from $T_L$ to $T_5$ was defined. For the patient level analysis, 1 implant per patient was randomly selected for data extraction. The metric variables with mean, standard deviations, median, quartiles, minimum and maximum were described. Categorical variables were summarized by counts and proportions of the categories. The comparisons of the group medians of the metric variables were performed with nonparametric methods (Wilcoxon-Mann-Whitney (WMW) test) because of the small samples sizes and non-normality of the data. Also, the changes over time were analyzed nonparametric with the Wilcoxon-signed rank test for each group. The proportions of the categorical parameters were compared with the Chi-squares test (with exact derivation of the p-value).

# Results

## Demographic data

Demographic data have already been presented (Ebler, et al., 2016). In brief, 64 patients were included for the study and received a total number of 97 implants (68 upper jaw, 29 lower jaw). All implants were inserted between February and December 2009. None of the demographic data (mean patient age, distribution of male and female patients, type of reconstruction) did reveal statistically significant differences ($p < 0.05$).

At $T_5$, 57 patients did attend to the follow-up visit (Dropout rate 5y: 10.9 %). The reasons for drop-out were: passing away, moving abroad or not willing to come to the follow-up visit. These 57 patients had at $T_5$ reconstructions which were supported by 48 S1 and 41 S2 implants (implant level analysis). For the patient level analysis, in which only 1 implant per patient was randomly selected for analysis, 29 S1 implants and 28 S2 implants were followed up at 5-years ($T_5$).

## Types of reconstructions

The types of reconstructions present at $T_5$, are listed in Table 1. At $T_5$ on the implant level, 48 S1 and 41 S2 implant reconstructions were included in the analysis. On the patient level, 29 S1 and 28 S2 reconstructions were included in the analysis.

## Survival rates

During the 5-year follow-up, 2 implants in group S1 had to be removed due to severe peri-implantitis with pus, suppuration and bone loss until the implant apex. Both implants were in the same patient. This resulted in a survival rate of 96.1% for group S1 on the implant level (2 implant failures). One implant in group S1 was considered as drop-out (patient did not attend the follow-up). On the patient level, 1 out of 29 S1 implants did not survive (severe peri-implantitis), resulting in a survival rate of 96.6%. In group S2, all implants survived until the 5-year follow-up examination, resulting in a survival

rate of 100% on both levels. On the patient level, the survival rates did not reach statistically significant differences (Chi-squares test: p = 1.000).

If the patients not attending the 5-year follow-up are considered as failures, the implant survival rate would be 94.1 % for S1 and 90.3 % for S2.

**Technical and biological complications on the patient level**

During the 5-year follow-up, in group S1, 14 technical complications were observed in 8 implants (some implants had more than one technical complication). This resulted in a technical complication rate of 24.2 % for S1. Technical complications in group S2 included 2 minor chippings in 2 implants, resulting in a complication rate of 6.5 %. The difference did not reach statistically significance (p = 0.0833).

At the time-point $T_1$, peri-implant mucositis with BOP at all 6 sites around the implant was observed in group S1 and S2 at 1 implant each (p = 1.000. At $T_3$, 1 peri-implant mucositis was detected in group S1, while 3 implants in group S2 were affected (p = 0.3474). At the 5-year follow-up ($T_5$), 1 implant in S1 showed signs of peri-implant mucositis and none of the S2 implants (p = 1.000). In summary, this results in a rate of peri-implant mucositis of 9.1 % for S1 and 12.9 % for S2 (p = 0.704). Peri-implantitis with bone loss ≥ 2 mm at the mesial and/or distal aspect was observed at the time-points $T_1$ (S1: 0 implant; S2: 1 implant; p = 0.484), $T_3$ (S1: 1 implant; S2: 0 implants; p = 1.000). In addition, as mentioned above, 1 implant was lost due to severe peri-implantitis. At the time-point $T_5$, no implant showed a bone loss of ≥ 2 mm.

Biological complications, including peri-implant mucositis, peri-implantitis and the loss of an implant due to peri-implantitis, were observed in 15.2% of the S1 implants (3 peri-implant mucositis, 1 peri-implantitis, 1 implant loss) and 16.1% of the S2 implants (4 peri-implant mucositis, 1 peri-implantitis) over an observation period of 5 years. The difference did not reach statistically significance (p = 1.000).

**Technical and biological complications on the implant level**

From $T_L$ to $T_5$, 15 S1 implants were affected by 39 technical complications: 9 minor chipping, 2 major chipping, 5 screw fractures, 19 screw loosening, 5 abutment fractures, 2 implant crowns, which had to

be removed. One patient with 4 implants contributed with 18 complications to these 39 complications. Another patient with 1 implant, suffered from 6 complications totally. In group S2, 6 technical complications (5 minor chipping, 1 major chipping) were seen in 5 implants.

On the biological level, peri-implant mucositis was observed in 3 cases in S1 and in 7 cases in S2 during the 5-year observation period. Four implants in group S1 and 3 implants in S2 showed a marginal bone level of ≥ 2 mm beneath the implant shoulder at the mesial and/or distal aspect during this time-period.

**Radiographic results**

A full overview of the radiographic results reported on the patient level is given in Table 2 (implant level: supplement, Table S1). The relative distances between the implant shoulder and the bone crest ranged at the time-point $T_5$ from -1.69 to 1.01 (S1) and from -0.74 to 1.19 mm (S2). Negative values indicate the implant shoulder being located more apically relative to the bone crest. From $T_L$ to $T_5$, the medians and the interquartiles Q1 and Q3 of the mean marginal bone level changes were 0.25 mm (Q1: 0.00 mm; Q3: 0.37 mm) for S1 and 0.30 mm (Q1: 0.00 mm; Q3: 0.50 mm) for S2 (intergroup comparison based on WMW test: $p = 0.370$). Therefore, the null-hypothesis that the medians of the groups S1 and S2 do not differ regarding this parameter could not be rejected.

Regarding the bone level changes from the time-point $T_L$ to $T_5$, the median changes of the mean marginal bone level amounted to a gain of 0.15 mm in group S1 and a loss of 0.14 mm in group S2 (intergroup comparison based on WMW test: $p = 0.033$). The time-effect was significant for group S2 (Wilcoxon signed rank test: $p = 0.033$), but not for S1 (Wilcoxon signed rank test: $p = 0.054$).

**Clinical outcome measures**

The results of the clinical outcomes on the patient level are presented in Table 3 for all time-points (implant level: supplement Table S2). The parameters BOP, PII and REC did not significantly change between $T_L$ and $T_5$ ($p > 0.050$). No group differences were found comparing S1 and S2 for the parameters BOP and PII ($p > 0.050$). The group difference was however significant for the parameter REC (Wilcoxon signed rank test: $p = 0.029$). In addition, the mean PD, significantly increased from $T_L$

to $T_5$ in group S2 by 0.42 mm (Wilcoxon signed rank test: $p = 0.003$). The median comparison between the groups reached a statistically significant difference (WMW test: $p = 0.018$).

## Discussion

The present 5-year RCT comparing 2 implant systems on the implant and restorative level demonstrated: i) minimal differences for all outcome measures between the two groups, ii) high survival rates of the implants and reconstructions, iii) stable marginal bone levels, iv) a minimal number of biological complications and, v) a high rate of technical complications for S1 only. The outcomes are to some extent limited by the fact that no power analysis was performed to to determine an appropriate sample size. Furthermore, no efforts were undertaken to assess the materials of the reconstructions.

On the patient level, the survival rates for the 2 systems were not statistically significant different. The survival rates, ranging from 96.6 to 100%, are in accordance to the results known from systematic reviews. They report on survival rates higher than 95% after 5 years for dental implants, supporting different types of FDPs (Albrektsson, Donos, Working, 2012; Jung, et al., 2012; Pjetursson, Thoma, Jung, Zwahlen, Zembic, 2012). The 2 implant systems were randomly selected to be placed in different non-standardized clinical situations. The high survival rates exhibited, support the use of these 2 implant systems to be placed on a daily basis in various clinical indications supporting fixed FDPs.

Osseointegrated implants present beside the high survival rates, only minimal marginal bone level changes on the long-term (Moraschini, Poubel, Ferreira, Barboza Edos, 2015). A systematic review including 10 prospective studies, 9 retrospective studies and 4 RCTs, found a mean marginal bone loss of 1.3 mm, ranging from 0.1 to 2.67 mm over 13.4 years. In the present study, the relative distances between the implant shoulder and the bone crest ranged from – 1.69 to 1.19 mm after 5 years. From loading to the 5-year follow-up, a median marginal bone level change of 0.25 and 0.30 mm was observed. A recently published large-scale clinical analysis included 588 patients having received dental implants of different implant providers (Derks, et al., 2016). After 9 years, the mean bone loss amounted to 0.63 mm on the patient level and 0.72 mm on the implant-level (Derks, et al., 2016). Thus, the present marginal bone levels and the respective changes are consistent with those reported in these studies and show stable results over a 5-year observation period.

Regarding the occurrence of biological complications, peri-implantitis on the patient level was observed in one S2 implant after 1 year and in one S1 implant after 3 years. In addition, two S1 implants were lost in one patient due to severe peri-implantitis. Based on an epidemiological study, it is known that over an observation period of 5 to 10 years, 10% of the implants and 20% of the patients are affected by peri-implantitis (Mombelli, Muller, Cionca, 2012). In both groups lower incidences were observed. However, it has to be stated that the case definitions of peri-implantitis are not consistent. In this study a bone loss of at least 2 mm at the mesial and/or distal aspect was rated as peri-implantitis. According to the very recent published recommendations from the «World Workshop on the Classification of Periodontal and Peri-Implant Diseases and Conditions», another definition would have been recommended (Berglundh, et al., 2018). The diagnosis of peri-implantitis requires a presence of bleeding and/or suppuration on gentle probing, an increased probing depth compared to previous examinations and a presence of bone loss beyond crestal bone level changes resulting from bone remodeling (Berglundh, et al., 2018). In the absence of previous radiographs, they state implants with a presence of bleeding on probing and/or suppuration, a probing depth of at least 6 mm and bone levels of at least 3 mm apical of the most coronal portion of the intraosseous part as affected by peri-implantitis (Berglundh, et al., 2018). According to the latter definition, the rate of peri-implantitis was presumably even lower than specified in the epidemiological studies. In terms of the occurrence of per-implant mucositis, 9.1% of the S1 and 12.9% of the S2 implants showed respective signs with BOP at all 6 sites around the implant. In the above cited large-scale study, 32% of the patients exhibited peri-implant mucositis (Derks, et al., 2016). In summary, for both implant systems, a minimal number of biological complications was observed and the rate of occurrence for peri-implant mucositis or peri-implantitis was when compared to other studies low.

Technical complications included minor and major chippings, screw loosening and abutment fractures. During the 5-year follow-up, technical complications were mostly observed in group S1, while in group S2 a low number of events occurred. The rates for technical complications were 24.2% for S1 and 6.5% for S2, without reaching statistically significance. The most common complications were minor chipping and screw loosening. Accordingly, a study evaluating the rate of technical complications in

the same implants as used in the group S1, found 6 technical complications in 52 FDPs (Wennstrom, Ekestubbe, Grondahl, Karlsson, Lindhe, 2004). A total of 6 complications occurred during the 5-year observation period: 3 screw loosening and 3 minor chippings (Wennstrom, et al., 2004). As seen in the present study, a large number of the affected patients experiences technical complications more than once (Karlsson, et al., 2018). For the implants as used in group S2, a study revealed one minor chipping out of 15 FDPs after an observation period of 3 years (Ioannidis, et al., 2015). It can therefore be concluded that, overall, a high rate of technical complications occurred in the present study.

## Conclusions

The present 5-year RCT comparing two implant systems found minimal differences for all clinical outcome measures between the two groups. By using one of these two implant systems, a high survival rate on the implant and on the level of the reconstruction can be anticipated after 5 years. A low number of biological complications with a minimal amount of marginal bone loss, the occurrence of per-implant mucositis and/or peri-implantitis can be expected. On the prosthetic level, a high number of technical complications can– predominantly in FDPs supported by implants of type S1 –be estimated, however not statistically significant different from S2.

**Acknowledgements and conflict of interest**

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**Table 1 - Type of reconstructions on implant and patient level for both implant systems (S1 and S2)**

| | Implant level | | Patient level | |
|---|---|---|---|---|
| | **S1** | **S2** | **S1** | **S2** |
| **ISSC** | 26 | 10 | 18 | 8 |
| **ISSC splinted** | 4 | 2 | 2 | 0 |
| **FDPs** | 11 | 16 | 4 | 9 |
| **ICFDPs** | 7 | 13 | 5 | 11 |
| **Total Number** | 48 | 41 | 29 | 28 |

ISSC = implant-supported single crowns; ISSC splinted = splinted implant supported single crowns; MUFDP = implant-supported multi-unit fixed dental prostheses; ICFDPs = implant-supported FDPs with cantilever extensions

**Table 2 - Radiographic data of marginal bone levels (DIB) at the time of insertion (T1), at the time of loading (TL), the 3-year (T3) and the 5-year (T5) follow-up examination, including the changes between different time-points. Patient-level analysis with means, standard deviations (SD), medians, interquartile ranges (IQR), range from minimum to maximum for both implant systems (S1 and S2).**

| | | S1 | | | | | | | S2 | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **DIB** | **n** | **Mean ± SD (mm)** | **Q1** | **Median (mm)** | **Q3** | **Range (mm) min to max** | **Paired P-value** | | **n** | **Mean ± SD (mm)** | **Q1** | **Median ± IQR (mm)** | **Q3** | **Range (mm) min to max** | **Paired P-value** | **P-value** |
| **Ti** | **31** | -1.30 ± 1.00 | -1.80 | -1.37 | -0.66 | -4.01 to [illegible] | NA | | **31** | -1.26 ± 1.22 | -1.73 | -1.20 | -0.62 | -4.92 to [illegible] | NA | 0.554 |
| **TL** | **33** | 0.29 ±0.44 | 0.16 | 0.37 | 0.58 | -1,10 to [illegible] | NA | | **31** | 0.22 ± 0.44 | 0.00 | 0.09 | 0.37 | -0.32 to [illegible] | NA | 0.027 |
| **T1** | **32** | 0.37 ± 0.39 | 0.26 | 0.37 | 0.57 | 1.22 to 0.97 | NA | | **31** | 0.39 ± 1.03 | 0.00 | 0.14 | 0.38 | -0.44 to [illegible] | NA | 0.007 |
| **T3** | **29** | 0.03 ± 0.56 | -0.15 | 0.00 | 0.25 | -1.66 to 1.38 | NA | | **29** | 0.24 ± 0.59 | 0.00 | 0.20 | 0.60 | -1.50 to 1.55 | NA | 0.082 |
| **T5** | **29** | 0.13 ± 0.54 | 0.00 | 0.25 | 0.37 | -1.69 to 1.01 | NA | | **28** | 0.34 ± 0.45 | 0.00 | 0.30 | 0.50 | -0.74 to 1.19 | NA | 0.370 |
| **TL-Ti** | **31** | 1.58 ± 0.93 | 0.78 | 1.62 | 2.27 | -0.44 to 3.39 | 0.000 | | **31** | 1.48 ± 1.16 | 0.69 | 1.16 | 2.03 | -0.17 to 4.92 | 0.000 | 0.3789 |
| **T1-TL** | **32** | 0.04 ± 0.23 | -0.10 | 0.01 | 0.15 | -0.55 to 0.71 | 0.383 | | **31** | 0.17 ± 0.86 | -0.04 | 0.00 | 0.10 | -0.49 to 4.68 | 0.528 | 0.8852 |
| **T3-TL** | **29** | -0.31 ± 0.52 | -0,71 | -0.26 | -0.15 | -1.32 to 1.00 | 0.001 | | **29** | -0.00 ± 0.49 | -0.24 | 0.06 | 0.24 | -1.51 to 1.49 | 0.889 | 0.0041 |
| **T5-TL** | **29** | -0.18 ± 0.47 | -0.33 | -0.15 | 0.07 | -2.11 to 0.40 | 0.054 | | **28** | 0.10 ± 0.35 | -0.02 | 0.14 | 0.26 | -0.76 to 0.83 | 0.033 | 0.0070 |

P-values for the patient-level analysis were calculated with the nonparametric Mann-Withney U-test and nonparametric paired Wilcoxon test to assess the influence of time.
* Represents a statistically significant difference.

**Table 3 - Clinical outcomes for both implant systems (S1 and S2) at the time of loading (TL), at the 1-year (T1), the 3-year (T3) and the 5-year (T5) follow-up examination with the respective changes over time. Patient-level analysis with means, standard deviations (SD), medians, interquartile ranges (IQR), range from minimum to maximum for both implant systems (S1 and S2).**

| | | S1 | | | | | | S2 | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Mean ± SD (mm) | Q1 | Median (mm) | Q3 | Range (mm) min to max | Paired P-value | Mean ± SD (mm) | Q1 | Median (mm) | Q3 | Range (mm) min to max | Paired P-value | P-value |
| **PD** | | | | | | | | | | | | | | |
| | **TL** | 3.13 ± 0.51 | 3.00 | 3.17 | 3.50 | 1.67 to 4.17 | NA | 2.83 ± 0.88 | 2.50 | 3.00 | 3.33 | 0.00 to 4.33 | NA | 0.072 |
| | **T1** | 3.14 ± 0.53 | 2.80 | 3.33 | 3.50 | 1.83 to 4.33 | NA | 3.04 ± 0.66 | 2.67 | 3.17 | 3.33 | 2.00 to 5.00 | NA | 0.356 |
| | **T3** | 3.46 ± 0.96 | 3.00 | 3.00 | 4.00 | 2.00 to 6.33 | NA | 3.14 ± 0.66 | 2.67 | 3.00 | 3.67 | 1.67 to 4.33 | NA | 0.362 |
| | **T5** | 3.19 ± 0.39 | 3.00 | 3.17 | 3.33 | 2.00 to 4.00 | NA | 3.33 ± 0.57 | 3.00 | 3.25 | 3.67 | 2.33 to 5.00 | NA | 0.504 |
| | **T1-TL** | 0.01 ± 0.36 | -0.17 | 0.00 | 0.33 | -0.67 to 0.50 | 1 | 0.21 ± 0.76 | -0.17 | 0.00 | 0.50 | -0.67 to 3.50 | 0.244 | 0.270 |
| | **T3-TL** | 0.34 ± 0.95 | -0.17 | 0.00 | 0.67 | -1.50 to 3.33 | 0.072 | 0.33 ± 1.02 | -0.33 | 0.25 | 0.83 | -1.33 to 4.00 | 0.08 | 0.970 |
| | **T5-TL** | 0.06 ± 0.65 | -0.50 | 0.00 | 0.34 | -1.00 to 1.67 | 0.825 | 0.48 ± 0.92 | 0.16 | 0.42 | 0.92 | -1.50 to 3.67 | 0.003 | 0.018 |
| **BOP** | | | | | | | | | | | | | | |
| | **TL** | 0.24 ± 0.22 | 0.00 | 0.17 | 0.50 | 0.00 to 0.67 | NA | 0.21 ± 0.18 | 0.00 | 0.17 | 0.33 | 0.00 to 0.50 | NA | 0.597 |
| | **T1** | 0.25 ± 0.20 | 0.17 | 0.17 | 0.33 | 0.00 to 1.00 | NA | 0.27 ± 0.25 | 0.00 | 0.33 | 0.50 | 0.00 to 1.00 | NA | 0.629 |
| | **T3** | 0.31 ± 0.28 | 0.00 | 0.33 | 0.50 | 0.00 to 1.00 | NA | 0.33 ± 0.35 | 0.00 | 0.25 | 0.67 | 0.00 to 1.00 | NA | 0.879 |
| | **T5** | 0.26 ± 0.20 | 0.17 | 0.17 | 0.33 | 0.00 to 1.00 | NA | 0.30 ± 0.26 | 0.17 | 0.33 | 0.33 | 0.00 to 0.83 | NA | 0.709 |
| | **T1-TL** | 0.01 ± 0.23 | -0.17 | 0.00 | 0.17 | -0.50 to 0.50 | 0.953 | 0.06 ± 0.27 | -0.17 | 0.00 | 0.17 | -0.50 to 0.67 | 0.212 | 0.464 |
| | **T3-TL** | 0.08 ± 0.30 | -0.17 | 0.02 | 0.33 | -0.33 to 0.83 | 0.050 | 0.13 ± 0.36 | -0.17 | 0.00 | 0.50 | -0.50 to 0.67 | 0.029 | 0.579 |
| | **T5-TL** | 0.03 ± 0.33 | -0.17 | 0.02 | 0.17 | -0.50 to 0.83 | 0.361 | 0.10 ± 0.30 | -0.17 | 0.08 | 0.33 | -0.50 to 0.67 | 0.029 | 0.404 |
| **PII** | | | | | | | | | | | | | | |
| | **TL** | 0.07 ± 0.13 | 0.00 | 0.00 | 0.17 | 0.00 to 0.50 | NA | 0.08 ± 0.15 | 0.00 | 0.00 | 0.17 | 0.00 to 0.67 | NA | 0.600 |
| | **T1** | 0.05 ± 0.12 | 0.00 | 0.00 | 0.00 | 0.00 to 0.50 | NA | 0.05 ± 0.11 | 0.00 | 0.00 | 0.00 | 0.00 to 0.33 | NA | 0.724 |
| | **T3** | 0.13 ± 0.25 | 0.00 | 0.00 | 0.17 | 0.00 to 1.00 | NA | 0.19 ± 0.30 | 0.00 | 0.00 | 0.33 | 0.00 to 1.00 | NA | 0.508 |
| | **T5** | 0.12 ± 0.19 | 0.00 | 0.00 | 0.17 | 0.00 to 0.67 | NA | 0.21 ± 0.29 | 0.00 | 0.00 | 0.33 | 0.00 to 1.00 | NA | 0.294 |
| | **T1-TL** | -0.02 ± 0.13 | 0.00 | 0.00 | 0.00 | -0.50 to 0.17 | 0.862 | -0.03 ± 0.16 | 0.00 | 0.00 | 0.00 | -0.67 to 0.33 | 0.352 | 0.644 |
| | **T3-TL** | 0.06 ± 0.29 | 0.00 | 0.00 | 0.17 | -0.50 to 0.83 | 0.137 | 0.11 ± 0.32 | 0.00 | 0.00 | 0.17 | -0.50 to 1.00 | 0.027 | 0.736 |
| | **T5-TL** | 0.05 ± 0.22 | 0.00 | 0.00 | 0.17 | -0.50 to 0.50 | 0.117 | 0.13 ± 0.29 | 0.00 | 0.00 | 0.33 | -0.33 to 1.00 | 0.010 | 0.552 |

P-values for the patient-level analysis were calculated with the nonparametric Mann-Withney U-test and nonparametric paired Wilcoxon test to assess the influence of time. * Represents a statistically significant difference. NA: not applicable; PPD = mean probing depth; BOP = mean bleeding on probing; PII = mean plaque control record; REC = mean recession.

**Table 4 - Radiographic data of marginal bone levels (DIB) at the time of insertion (T1), at the time of loading (TL), the 3-year (T3) and the 5-year (T5) follow-up examination, including the changes between different time-points. Implant-level analysis with means, standard deviations (SD), medians, interquartile ranges (IQR), range from minimum to maximum for both implant systems (S1 and S2).**

| | | S1 | | | | | | S2 | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **DIB** | **n** | **Mean ± SD (mm)** | **Q1** | **Median (mm)** | **Q3** | **Range (mm) min to max** | **n** | **Mean ± SD (mm)** | **Min** | **Q1** | **Median** | **Q3** | **Range (mm) min to max** |
| **Ti** | **50** | -1.07 ± 0.94 | -1.75 | -1.01 | -0.40 | -4.01 to | **43** | -1.21 ± 1.13 | -4.92 | -1.63 | -1.15 | -0.62 | -4.92 to |
| **TL** | **54** | 0.39 ±0.53 | 0.200 | 0.37 | 0.58 | -1.09 to | **43** | 0.21 ± 0.34 | -0.42 | 0.00 | 0.10 | 0.40 | -0.42 to |
| **T1** | **52** | 0.50 ± 0.60 | 0.29 | 0.39 | 0.57 | -1.22 to | **43** | 0.34 ± 0.88 | -0.44 | 0.00 | 0.15 | 0.40 | -0.44 to |
| **T3** | **47** | 0.05 ± 0.70 | -0.20 | 0.00 | 0.25 | -1.66 to 3.00 | **41** | 0.29 ± 0.61 | -1.50 | 0.00 | 0.20 | 0.60 | -1.50 to 1.74 |
| **T5** | **45** | 0.18 ± 0.66 | 0.00 | 0.20 | 0.36 | -1.69 to 2.92 | **41** | 0.42 ± 0.70 | -0.86 | 0.00 | 0.34 | 0.56 | -0.86 to 3.48 |
| **TL-Ti** | **50** | 1.44 ± 0.94 | 0.69 | 1.37 | 2.22 | -0.44 to 3.50 | **43** | 1.42 ± 1.08 | -0.17 | 0.69 | 1.16 | 2.00 | -0.17 to 4.92 |
| **T1-TL** | **52** | 0.07 ± 0.28 | -0.09 | 0.02 | 0.15 | -0.55 to 0.95 | **43** | 0.13 ± 0.75 | -0.49 | -0.09 | 0.00 | 0.10 | -0.49 to 4.68 |
| **T3-TL** | **47** | -0.33 ± 0.60 | -0,73 | -0.28 | -0.11 | 1.91 to 1.49 | **40** | -0.02 ± 0.47 | -1.51 | -0.22 | 0.07 | 0.26 | -1.51 to 1.49 |
| **T5-TL** | **45** | -0.20 ± 0.53 | -0.37 | -0.15 | 0.04 | -2.11 to 1.40 | **40** | 0.12 ± 0.38 | -0.80 | -0.03 | 0.15 | 0.30 | -0.80 to 1.16 |

**Table 3 - Clinical outcomes for both implant systems (S1 and S2) at the time of loading (TL), at the 1-year (T1), the 3-year (T3) and the 5-year (T5) follow-up examination with the respective changes over time. Implant-level analysis with means, standard deviations (SD), medians, interquartile ranges (IQR), range from minimum to maximum for both implant systems (S1 and S2).**

| | | S1 | | | | | | S2 | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | n | Mean ± SD (mm) | Q1 | Median (mm) | Q3 | Range (mm) min to max | n | Mean ± SD (mm) | Min | Q1 | Median (mm) | Q3 | Range (mm) min to max |
| **PD** | | | | | | | | | | | | | | |
| | **TL** | **53** | 3.10 ± 0.55 | 2.83 | 3.17 | 3.50 | 1.67 to 4.67 | **43** | 2.89 ± 0.78 | 0.00 | 2.50 | 3.00 | 3.33 | 0.00 to 4.33 |
| | **T1** | **53** | 3.14 ± 0.73 | 2.67 | 3.17 | 3.50 | 1.67 to 5.67 | **43** | 3.07 ± 0.61 | 2.00 | 2.67 | 3.17 | 3.50 | 2.00 to 5.00 |
| | **T3** | **47** | 3.40 ± 0.80 | 3.00 | 3.00 | 6.67 | 2.00 to 6.33 | **42** | 3.37 ± 0.82 | 1.67 | 3.00 | 3.33 | 4.00 | 1.67 to 5.67 |
| | **T5** | **46** | 3.21 ± 0.39 | 3.00 | 3.17 | 3.33 | 2.00 to 4.17 | **41** | 3.39 ± 0.63 | 2.33 | 3.00 | 3.33 | 3.67 | 2.33 to 5.33 |
| | **T1-TL** | **53** | 0.04 ± 0.58 | -0.33 | 0.00 | 0.33 | -0.83 to 2.66 | **43** | 0.19 ± 0.70 | -1.00 | -0.17 | 0.00 | 0.50 | -1.00 to 3.50 |
| | **T3-TL** | **47** | 0.34 ± 0.82 | -0.17 | 0.17 | 0.67 | -1.50 to 3.33 | **42** | 0.49 ± 1.02 | -1.33 | -0.17 | 3.33 | 1.00 | -1.33 to 4.00 |
| | **T5-TL** | **46** | 0.14 ± 0.66 | -0.33 | 0.08 | 0.50 | -1.50 to 1.83 | **40** | 0.44 ± 0.78 | -1.50 | 0.17 | 0.42 | 0.67 | -1.50 to 3.67 |
| **BOP** | | | | | | | | | | | | | | |
| | **TL** | **53** | 0.25 ± 0.21 | 0.00 | 0.17 | 0.50 | 0.00 to 0.67 | **43** | 0.24 ± 0.18 | 0.00 | 0.00 | 0.17 | 0.33 | 0.00 to 0.50 |
| | **T1** | **53** | 0.67 ± 0.20 | 0.67 | 0.17 | 0.33 | 0.00 to 1.00 | **43** | 0.27 ± 0.23 | 0.00 | 0.00 | 0.17 | 0.50 | 0.00 to 1.00 |
| | **T3** | **48** | 0.26 ± 0.24 | 0.08 | 0.17 | 0.33 | 0.00 to 1.00 | **42** | 0.36 ± 0.37 | 0.00 | 0.00 | 0.17 | 0.67 | 0.00 to 1.00 |
| | **T5** | **46** | 0.24 ± 0.22 | 0.00 | 0.17 | 0.33 | 0.00 to 1.00 | **41** | 0.33 ± 0.27 | 0.00 | 0.17 | 0.33 | 0.33 | 0.00 to 0.83 |
| | **T1-TL** | **53** | 0.01 ± 0.23 | -0.17 | 0.00 | 0.17 | -0.50 to 0.50 | **43** | 0.03 ± 0.26 | -0.50 | -0.17 | 0.00 | 0.17 | -0.50 to 0.67 |
| | **T3-TL** | **48** | 0.03 ± 0.27 | -0.17 | 0.00 | 0.17 | -0.33 to 0.83 | **42** | 0.13 ± 0.36 | -0.50 | -0.17 | 0.00 | 0.50 | -0.50 to 0.83 |
| | **T5-TL** | **46** | 0.00 ± 0.31 | -0.17 | 0.00 | 0.17 | -0.50 to 0.83 | **40** | 0.08 ± 0.28 | -0.50 | -0.67 | 0.00 | 0.33 | -0.50 to 0.67 |
| **PII** | | | | | | | | | | | | | | |
| | **TL** | **53** | 0.05 ± 0.11 | 0.00 | 0.00 | 0.00 | 0.00 to 0.50 | **43** | 0.07 ± 0.14 | 0.00 | 0.00 | 0.00 | 0.17 | 0.00 to 0.67 |
| | **T1** | **53** | 0.04 ± 0.10 | 0.00 | 0.00 | 0.00 | 0.00 to 0.50 | **43** | 0.04 ± 0.10 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 to 0.33 |
| | **T3** | **48** | 0.13 ± 0.22 | 0.00 | 0.00 | 0.17 | 0.00 to 1.00 | **42** | 0.23 ± 0.35 | 0.00 | 0.00 | 0.00 | 0.33 | 0.00 to 1.00 |
| | **T5** | **46** | 0.12 ± 0.18 | 0.00 | 0.00 | 0.17 | 0.00 to 0.67 | **41** | 0.25 ± 0.34 | 0.00 | 0.00 | 0.00 | 0.33 | 0.00 to 1.00 |
| | **T1-TL** | **53** | -0.01 ± 0.11 | 0.00 | 0.00 | 0.00 | 0.50 to '0.17 | **43** | -0.03 ± 0.15 | -0.67 | 0.00 | 0.00 | 0.00 | -0.67 to 0.33 |
| | **T3-TL** | **48** | 0.08 ± 0.26 | 0.00 | 0.00 | 0.17 | 0.50 to' 0.83 | **42** | 0.16 ± 0.37 | -0.50 | 0.00 | 0.00 | 0.33 | -0.50 to 1.00 |
| | **T5-TL** | **46** | 0.07 ± 0.20 | 0.00 | 0.00 | 0.17 | -0.50 to 0.50 | **40** | 0.16 ± 0.35 | -0.33 | 0.00 | 0.00 | 0.33 | -0.33 to 1.00 |